K014063 p1/2

CNSystems
The Brain & Heart Company

FEB 0 7 2002

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1. Summary and Certification

1. 1 Premarket Notification 510(k) Summary

SUBSTANTIAL EQUIVALENCE
Identification of predicate devices, model and manufacturer:

Predicate device:	CardioDynamics BioZ.pc
Model:	BZ-500/BZ-501
Manufacturer:	CardioDynamics International Corporation
Predicate Device 510(k):	K001081
Reason for Submission:	New device

Predicate device:	Ohmeda Finapres
Model:	2350 Finapres
Manufacturer:	Ohmeda Medical
Predicate Device 510(k):	K880572
Reason for Submission:	New device

The Task Force® Monitor 3040 is substantially equivalent to the BioZ.pc in terms of design, intended use and principle of operation. Furthermore the Task Force® Monitor 3040 is substantially equivalent to the Finapres 2350 in terms of intended use and principle of operation.
The Task Force® Monitor 3040 simply combines the noninvasive hemodynamic patient monitoring principle of the BioZ.pc system with the noninvasive continuous blood pressure measurement of the Finapres 2350 device. The patient instrumentation electronics (which provides all data acquisition, isolation and defib protection) are separated from the PC which interacts with the user. The software is pre-installed on the PC, a backup copy of the software is enclosed.

The software of the Task Force® Monitor 3040 controls the hardware, displays the hemodynamic parameters and gives the user the possibility to store the measurement data on the hard disk (like the BioZ.pc). Both devices (Task Force® Monitor 3040 and BioZ.pc) use a software integrity check when the monitoring software is first activated, to insure that no corruption has occurred of any of the operation software used by the device. Furthermore the TFM repeats this check at the beginning of each measurement.

A difference is the software installation kit: while CardioDynamics encloses a software installation kit diskette, the TFM software is pre-installed on the PC. Furthermore Cardiodynamics allows only particular models of notebook PC's which have been previously validated by CardioDynamics, due to the short life cycle of state-of-the-art PC's, CNSystems ships a fully tested PC with the TFM system.

The Task Force® Monitor 3040, the BioZ.pc system and the Finapres device are portable in design and for use in the hospital, outpatient and clinical settings. The intended use of the Task Force® Monitor 3040 is to noninvasively measure a patient's hemodynamic parameters using Impedance Cardiography (ICG) and continuous blood pressure (contBP) measurement. Monitoring is accom-

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plished by attaching 3 double electrodes and a neutral electrode for ICG (1 in the neck and 2 on each side of the thorax), 4 electrodes for ECG, one finger cuff for continuous blood pressure measurement and one upper arm cuff for oscillometric blood pressure measurement. ICG is injecting a minimal current through the upper electrodes and reading the returning voltage waveform from the inner electrodes.

The Task Force® Monitor 3040 uses the same methods and algorithms for calculating the patient's hemodynamic parameters as both predicate devices.

Blood pressure is measured in two ways: the absolute blood pressure values are measured with an oscillometric device and the continuous blood pressure changes are measured with the contBP (same method as the Finapres device). The TFM system automatically corrects the continuous blood pressure trend to the absolute values of the oscillometric device. Due to the state-of-the-art electronic components, the blood pressure is monitored contiguously without any interruptions while the Finapres device has to interrupt the measurement for resetting the set point from time to time.

Both the Task Force® Monitor 3040 and the BioZ.pc are IBM PC-based products, which differ only in the version of the operation system.

The Task Force® Monitor 3040 (TFM) is substantially equivalent to its predicate devices, the BioZ.pc currently marketed by CardioDynamics International Corporation and the Finapres 2350. The TFM has the same intended use and no technological differences which would rise new questions concerning safety and effectiveness.

The justification for this substantial equivalence determination is presented below.

Substantial equivalence is shown in the following table (on the next page).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 7 2002

CNSystems Medizintechnik GmbH
c/o Mr. Mark Job
TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K014063
Trade Name: Task Force® Monitor 3040
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II (two)
Product Code: DSB
Dated: January 31, 2002
Received: January 31, 2002

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

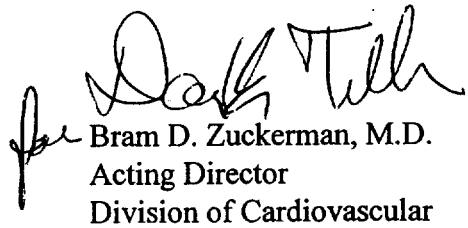
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014063

Device Name: **Task Force® Monitor 3040**

Indications For Use:

The Task Force® Monitor 3040 (TFM) is intended to noninvasively measure and display a patient's hemodynamic parameters using Impedance Cardiography (ICG), Electrocardiography (ECG), oscillometric Blood Pressure (oscBP) and continuous Blood Pressure (contBP). The TFM monitors continuously the subject's hemodynamic parameters without reporting any diagnosis.
Every measurement must be supervised by a medical trained professional. The Task Force® Monitor 3040 is a diagnoses aiding device and therefore not designed for vital sign monitoring or self-monitoring of patients.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014063